CLAIMS

1. A composition for nasal or buccal application comprising a distribution of multilayer microparticles in a base, at least one ingredient having activity on the mucosa of the nose/ throat being adsorbed within the layers of the microparticles so as to be progressively released over time in use.

2. Composition of Claim 1 in the form of an aerosolisable composition for nasal or buccal application by means of a spray, mousse or drench, a suspension in a suitable liquid base for direct oral or nasal administration, for example by oral ingestion, gargle, rinse or the like, or as a distribution of multilayer microparticles in a soluble solid or gel base, in particular for oral administration, for example as a pastille, lozenge or the like, the base material being such as to dissolve within the mouth and liberate the microparticles to allow them to find their site on the mucous membranes of the throat.

3. Composition of Claim 1 or 2 wherein multilayer microparticles are selected to exhibit good adhesion to the mucous membranes of the nose and/or throat.

4. Composition of any of Claims 1 to 3 wherein multilayer microparticles are small enough to be aerosolisable as a spray, for example of size in the range 0.1 – 10 μm.

5. Composition of any of Claims 1 to 4 wherein layers are structured to give slow release of the active ingredient over the desired time period, so that the spray gives sustained activity over time, for example providing for measurable activity (eg at least 50% of initial base line activity level) for a sustained period

of four or more hours, and ideally of for example 6 to 12 hours, to give overnight effectiveness.

6. Composition of any of Claims 1 to 5 wherein particle levels are of 10-25% within the composition.

7. Composition according to any of Claims 3 to 6 wherein the microparticles generally comprise polar structures with a positive surface charge, whereby adhesion to the mucosa of the nose or throat takes place as the tissue in the nose or throat tends to be negatively charged.

8. Composition according to any of Claims 1 to 7 wherein the microparticles comprise multiple layered structures formulated with one or more of and preferably examples of all of: surfactant layers (comprising any type of surfactant such an anionic, non-anionic, cationic, phospholipids and the like); polar media such as water, glycerol, PEG; and active binding materials comprising hydrophilic materials in the polar layers and hydrophobic materials in the surfactant layers.

9. Composition according to any of Claims 1 to 8 which includes 5 to 30% surfactant, 30 to 90% polar medium, and 1 to 50% active encapsulated agent, comprising hydrophilic and hydrophobic agents.

10. Composition according to any of Claims 1 to 8 which includes active ingredients with other activities, for example physical (moisturising, lubricating, cooling etc) or pharmacological (for example decongestant, anti-histamine, anti-bacterial, anti-inflammatory, analgesic etc).

11. Composition according to any of Claims 1 to 8 wherein the active ingredient comprises a mixture of lubricating and/or moisturising oils selected from the group comprising: Hyaluronic acid or sodium Hyaluronique, Glycerol, Calendula officinalis flower extract or glycerin extract, Guar hydroxypropyltrimonium chloride, Xanthan gum, Cellulose gum, Sodium chloride, Olivum (olive oil), Helianthus annus (sunflower oil), Prunus dulcis (sweet almond oil), Sesamum indicum (sesame oil), Aloe vera, Aloe barbadensis, Euphorbium officinarum, Oxymetazoline hydrochloride, Lacto-peroxidase and combinations thereof.

12. Composition according to any of Claims 1 to 8 wherein the active ingredient comprises at least one decongestant, being an ingredient having a chemical or pharmacological or other effect of reducing airway congestion and/or limiting further airway mucus production

13. Composition according to any of Claims 1 to 8 wherein the active ingredient is selected from a natural oil, a pharmacalogically active synthetic preparation, or combination. Suitable examples include: Hyaluronic acid, Calendula officinalis flower extract or glycerin extract, Thymus vulgaris, Menthyl lactate, Mentha piperita (or any other mint/ peppermint derivative or extract), Lavendula augustifolia (or any other lavender derivative or extract), Phenylephrine hydrochloride, Pseudephedrine, Ascorbic acid (vitamin C), Acerola, Rumex crispus (yellow dock), Eucalyptus globulus (eucalyptus oil), Levmetamfetamine, Oxymetazoline hydrochloride, Propylhexedrine, Xylometazoline hydrochloride, Zincum Gluconicum, menthol, eugenol, cineol, rosemary oil (rosmarinus), summer savory oil (satureia hortensis), wild thyme oil (thymus serpyllum), firtree oil, lavendula vera oil, geranium oil,

cinnamon oil, Hawthorn extract (crataegus oxyacantha), rose hips extract (rosa canina), cypress oil (cupressus sempervirens), grapeseed oil and combinations thereof.

14. A composition according to any of Claims 1 to 13 wherein the liquid base is aqueous, for example comprising a saline or otherwise generally isotonic solution.

15. A composition according to any of Claims 1 to 14 comprising additional active ingredients having any further desired physical or pharmacological activity on the mucous membranes of the nose and/ or throat, including without limitation decongestants, breath-fresheners and deodorisers, lubricants, antibacterial and antiseptic compositions, anti-histamines, anti-inflammatory compositions, analgesics, and other medicaments and non- medicaments.

16. A composition according to any of Claims 1 to 15 for delivery by means of a spray dispenser, and in particular a nasal spray dispenser, comprising a base reservoir container containing a composition as hereinbefore described and a spray delivery system for example comprising a pump spray, the reservoir being fluidly connected to the spray delivery system, and the spray delivery system being adapted to draw, aerosolise and deliver a controlled dose from the reservoir to a subject in use.

17. A method for the preparation of a composition according to any of Claims 1 to 16 for the controlled delivery of an active ingredient over time *in situ* at the mucous membranes of the nose or throat of a human, non-human mammal or other animal comprises the steps of:

microencapsulating at least one ingredient having activity on the mucosa of the nose/ throat within or on the layer surfaces of a multilayer microparticle; distributing the ingredient within a suitable inactive base material serving as a means to deliver the microspheres to the active site for example suspending in a liquid base or distributing in a soluble solid base.

18. A method according to claim 17, wherein the encapsulation is conducted by mixing surfactants, active binding materials, an aqueous solvent phase, and other ingredients including active ingredients to form a homogenous lamellar liquid crystal phase under conditions of shear so as to form multilamellar microparticles.

19. A method according to claims 17 or 18, which comprises preparing a spray composition by preparing a suspension of a plurality of such particles in a liquid base and filling a spray dispenser of suitable design with the suspension, and in particular a nasal spray dispenser, comprising a base reservoir container containing a composition as hereinbefore described and a spray delivery system for example comprising a pump spray, the reservoir being fluidly connected to the spray delivery system, and the spray delivery system being adapted to draw, aerosolise and deliver a controlled dose from the reservoir to a subject in use.

20. A method according to any of claims 17 to 19, which comprises preparing a liquid suspension of microparticles for direct oral administration, for example by ingestion, gargle or rinse, or which comprises preparing a composition for oral administration distributed within a soluble solid or gel base, for example as a lozenge or pastille.

21. A method of delivering an active ingredient to the nose or throat of a human, non-human mammal or other animal subject for controlled release over time *in situ* at the mucous membranes of the subject comprises the steps of:

administering the composition according to any of claims 1 to 16 to the subject in such manner that the microparticles are directed towards a desired site on the mucus membrane of the subject.

22. The use of the composition of any of Claims 1 to 16 or an active microparticle as hereinbefore defined in progressive delivery of an active ingredient as hereinbefore defined.

23. A novel active microparticle as hereinbefore defined in any of Claims 1 to 16.

24. A novel active microparticle according to Claim 23 comprising active ingredients effective in the reduction of snoring or apnoea.